

List of Publications

Issue Summary for Topic #1, “Consideration of Labeling Claims for Transmissible Spongiform Encephalopathy (TSE) Agent Clearance in Plasma Derivatives”

TSE Advisory Committee Meeting, February 20, 2003

1. Cervenakova, L., et al. Factor VIII and transmissible spongiform encephalopathy: the case for safety. *Haemophilia* 8:67-85, 2002. Review article.
2. Bons, N., et al. Brain and buffy coat transmission of bovine spongiform encephalopathy to the primate *Microcebus murinus*. *Transfusion* 42: 513-16, 2002. Single case of transmission by buffy coat given i.c. to lemur.
3. Hunter, N., et al. Transmission of prion diseases by blood transfusion. *J. Gen. Virol.* 83:2897-2905, 2002. Sheep transfusion studies, using BSE and scrapie.
4. Guidance for Industry “Revised preventive measures to reduce the possible risk of transmission of CJD and vCJD by blood and blood products.” Current guidance for blood donor deferrals, published 1/2002.
(<http://www.fda.gov/cber/guidelines.htm>)
5. Cai, K., et al. Solvent-dependent precipitation of prion protein. *Biochimica et Biophysica Acta* 1597: 28-35, 2002. Variations in pH, ionic strength, and ethanol concentration conditions influence partitioning of Prp^{Sc}.
6. Stenland, C., et al. Partitioning of human and sheep forms of the pathogenic prion protein during the purification of therapeutic proteins from human plasma. *Transfusion* 42: 1497-1500, 2002. Partitioning of pathogenic prion protein in scaled-down plasma fractionation processes (Western blot assay).
7. Foster, P., et al. Studies on the removal of abnormal prion protein by processes used in the manufacture of human plasma products. *Vox Sang.* 78: 86-95, 2000. Partitioning of pathogenic prion protein in scaled-down plasma fractionation processes (Western blot assay).
8. Reichi, H.E. et al. Studies on the removal of a bovine spongiform encephalopathy-derived agent by processes used in the manufacture of human immunoglobulin. *Vox Sang.* 83:137-145, 2002. Partitioning of BSE infectivity in scaled-down plasma fractionation step, studied individually, and in series (bioassay).

9. Wadsworth, J.D.F. et al. Tissue distribution of protease resistant prion protein in variant CJD using a highly sensitive immunoblotting assay. *Lancet* 358: 171-80, 2001. Western blot assay for protease resistant prion protein in a single sample from a terminal vCJD patient (fig. 5).
10. Bruce, M.E. et al. Detection of variant CJD infectivity in extraneural tissues. *Lancet* 358: 208,9, 2001. Bioassay of buffy coat and plasma from two patients with vCJD, for infectivity.